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# Significant Improvement in Glycemic Outcomes in Type 2 Diabetes Patients: The Impact of 14-Day Personalized Coaching and Continuous Glucose Monitoring on Glycemic Variations

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***Abstract— Background***

***Continuous Glucose Monitoring (CGM) is a revolution in diabetes management as it helps provide continuous insights into glycemic variability (GV) including hypo- and hyperglycemic episodes. The aim of this study was to observe if CGM-directed personalized nutrition, progressive fitness, and mindfulness coaching by Sugarfit Diabetes Reversal and Management Program (SDRMP) improved glycemic parameters in patients with T2D.***

***Methods***

***CGM data from 2860 participants with type 2 diabetes (T2D) enrolled in SDRMP was collected between June 01, 2021, to June 30, 2022, and analyzed retrospectively. All participants wore the CGM device subcutaneously on the arm for 14 days. Such device efficiently transmitted the gathered data (i.e. glycemic trends) to a separate receiver, typically a smartphone application (Innovative Sugarfit app, Ragus Healthcare Private Limited, India). Patients participating in the study were instructed to periodically scan the sensor, ensuring continuous monitoring throughout the day.***

***Results***

***Of the 2860 participants, 2078 were males (72.63%) and 782 were female (27.34%). The mean age of participants was 46.5±10.7 years. The CGM captured one reading every 15 minutes for a total of 96 glucose readings every day for up to 14 days. There was a significant increase in time in range (TIR, 22.01%, p<0.001) from day 1 to day 14 through SDRMP'S personalized life coaching interventions. There was a significant correction in the time above range (TAR) by 28.21% and of time below range (TBR) by 78.63% (p<0.001 for both). The average estimated HbA1c decreased from 7.2±1.7 at baseline to 6.7±1.3 at day 14.***

***Interpretation***

***CGM-directed personalized lifestyle interventions showed improved TIR in patients with T2D. Valuable insights into daily and intra-day glycemic variations promotes better adherence to lifestyle modifications, ultimately leading to improved glycemic outcomes and reduced complications in diabetes.***

***Index Terms- Glycemic outcomes, type 2 diabetes, time in range, continuous glucose monitoring, personalized coaching***

## I. INTRODUCTION

Diabetes is one of the most rapidly growing chronic lifestyle diseases; type 2 diabetes (T2D) constitutes over 95% of all cases.[1] Globally, 537 million diabetes cases were reported, which are estimated to reach up to nearly 783 million by 2045.[2] The mortality rate from diabetes alone was 6.7 million in 2021.[3] There has been a dramatic rise in the diabetes prevalence in South-East Asia, particularly among people living in cities, due to urbanization and industrialization. In developing economies like India, an estimated 77 million individuals have diabetes, which is expected to rise to over 134 million by 2045.[2] Further, 10.3% to 24.7% of the Indians had prediabetes, according to the Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) data and using the World Health Organization (WHO) or American Diabetes Association (ADA) criteria for diagnosing prediabetes.[4]

In developing countries, T2D is vastly underdiagnosed leading to a wide range of diabetes-related complications and premature deaths.[2] Further, fluctuations in blood glucose (BG) (or glycemic variability, GV) is increasingly recognized to have a significant role in pathogenesis of diabetic complications, mortality rates, and other adverse clinical outcomes.[2,5] These GV related complications can be effectively managed/prevented by screening and monitoring BG levels at regular intervals.

Traditional BG monitoring methods like self-monitoring of blood glucose (SMBG) are cumbersome, need multiple pricks, and do not provide complete insights into the hypo- and hyperglycemic episodes.[1]

On the other hand, digital artificial intelligence (AI) driven technologies such as continuous glucose monitoring (CGM) provide the needed noninvasive pain-free technique for frequent monitoring of glycemic values.[1,6,7]

The CGM method can be used to assess the time in range (TIR) which is defined as the time spent by the BG in the target range of 70 and 180 mg/dL.[8] TIR was validated as an outcome measure for clinical trials complementing other components of glycemic control like blood glucose and glycosylated hemoglobin (HbA1c).[9] Additionally, time below range (TBR), defined as BG values <70 mg/dl and time above range (TAR), defined as BG values >180 mg/dl are also used to assess GV.[10]

CGM serves as a valuable tool for individuals with diabetes, enabling them to comprehend the fluctuations in their glucose levels throughout the day. Additionally, it provides healthcare providers with insights to prescribe precise targeted interventions or medications by visualizing trends in GV obtained through continuous monitoring of sensor glucose values at predetermined intervals using the CGM device.[7] Moreover, the learnings derived from CGM can be utilised by the expert diabetes coaches to support and guide their clients effectively. By gaining access to CGM insights, expert diabetes coaches can better understand their clients' glucose patterns, facilitating personalized guidance and assistance. This holistic approach empowers coaches to provide appropriate support in managing diabetes. This concept is increasingly being utilized for reversal of T2D. ‘Sugarfit Diabetes Reversal and Management Program’ (SDRMP) is one such diabetes reversal program providing technology-driven digital health management.

The aim of this study was to observe if there was an improvement in the glycemic trends as generated by the CGM device during 14 days of personalized lifestyle coaching of T2D patients enrolled in SDRMP.

## II. METHODS

This was a retrospective analysis conducted in individuals with T2D using CGM (Libre Pro, Abbott Diabetes Care, Inc, Alameda, CA) for a period of 14 days. The study was conducted from June 1, 2021 to June 30, 2022. The study included T2D patients ≥18 years, with HbA1c >6.5%, and willingness to participate in SDRMP (Sugarfit, Bangalore, India). Patients ≤18 years old, pregnant women, individuals with severe complications (chronic kidney diseases, chronic liver diseases, etc.), and individuals who did not have CGM readings for the entire duration of 14 days were excluded from the study.

This was an observational study and no medication was added or changed for the participants during the study period of 14 days. TIR, TBR and TBR were evaluated for the study period.

- Sugarfit Diabetes Reversal and Management Program

SDRMP is a multi-interventional approach model consisting of clinicians, nutritionists, and personalized fitness coaches, and over 450 modules of mindfulness. SDRMP included easily accessible reports based on the food and medication intake data provided by each participant and real-time glycemic data generated through CGM. The SDRMP team continuously tracked and monitored the progress of participants through digital technology which helped in understanding the metabolism and root cause of hyperglycemia in each individual. In India, SDRMP is presenting first of its kind retrospective analysis of a very large cohort of T2D patients.

- Continuous glucose monitoring

A CGM diabetes sensor was placed subcutaneously (back of the arm) for each participant for 14 days. Where, a small and delicate sensor electrode, featuring an ultra-thin filament, was carefully inserted just beneath the skin. This electrode was connected to a transmitter, which efficiently transmitted the gathered data to a separate receiver, typically a smartphone application.[1,11] This seamless connectivity was made possible through the innovative Sugarfit app, developed by Ragus Healthcare Private Limited, India. Patients participating in the study were instructed to periodically scan the sensor, ensuring continuous monitoring throughout the day. The sensor captured readings of interstitial fluid glucose and henceforth referred to as sensor glucose, and with the assistance of the Sugarfit app, glycemic trends were generated for each day of the study. Which enables individuals with diabetes to comprehend the fluctuations in their glucose levels throughout the day. The SDRMP coaches effectively interpreted the shared CGM data and engaged the patients in shared decision-making for better outcomes. No medication changes were done during this period.

- Statistical analysis

Continuous data were reported as mean ± standard deviation (SD) or median (IQR) while categorical data was described as number (%), unless otherwise indicated. A *p*-value less than 0.05 is considered to be statistically significant. The statistical data were analyzed using SPSS (IBM SPSS Statistics version 26.0, IBM Corp., USA).

## III. RESULTS

The study included 2860 participants; mean age 46.5±10.7 years; and 72.63% were males (table 1). The mean baseline HbA1c and fasting blood glucose (FBG) was 9.1±1.8% and 182.1±62.4 mg/dL, respectively (Table 1).

| Variables | N=2860, ±SD, % |
|---|---|
| Age (Years) | 46.7±10.7 |
| Gender | |
| Male | 2078 (72.65) |
| Female | 782 (27.34) |
| Weight (Kgs) | 76.7±14.5 |
| Body mass index (BMI) | 27.1±4.6 |
| Hemoglobin A1c (HbA1c, %) | 9.1±1.8 |
| Fasting Blood Sugar (FBS, mg/dL) | 182.1±62.4 |

Table 1 - Baseline characteristics of participants ( Data are mean ± SD or percentage unless otherwise indicated.)

The participant's readings were captured every 15 min with a total of 96 captured values per day. There were 1150 participants whose GV calculated through co-efficient of variation was more than 25. The average GV for the initial three days (days 2,3,4) was 30.62 which was reduced to 25.69 for the later three days (days 12,13,14).

Time spent in hours and improvement in percentage time spent in TIR, TBR, and TAR by day 14 is presented in table 2, table 3, and figure 1.

Table 2 - Time spent in hours

| | Time spent in hours | | | |
|---|---|---|---|---|
| Blood Glucose | Day 2,3,4 (average) | IQR (Q1 to Q3) | Day 12,13,14 (average ) | IQR (Q1 to Q3) |
| <70 mg/dL (TBR) | 0.71 | 0 to 0 | 0.15 | 0 to 0 |
| 70-180 mg/dL (TIR) | 41.16 | 21.3 to 62.5 | 50.22 | 38.8 to 67.8 |
| >180 mg/dL (TAR) | 30.13 | 8 to 51.8 | 21.63 | 4 to 33.3 |

IQR – Inter quartile range; TAR – Time above range; TBR – Time below range, TIR – Time in range.

Table 3 - Percentage time spent and improvement

| | Percentage of time spent | | | | |
|---|---|---|---|---|---|
| Blood Glucose | Day 2,3,4 (%) | Day 12,13,14 (%) | Increase in time spent (%) | Percentage improvement in time range (%) | *p*-value |
| <70 mg/dL (TBR) | 0.99 | 0.21 | -0.78 | 78.63 | <0.001 |
| 70-180 mg/dL (TIR) | 57.17 | 69.75 | 12.58 | 22.01 | <0.001 |

| | | | | | |
|---|---|---|---|---|---|
| >180 mg/dL (TAR) | 41.84 | 30.04 | -11.80 | 28.21 | <0.001 |

IQR – Inter quartile range; TAR – Time above range; TBR – Time below range, TIR – Time in range.

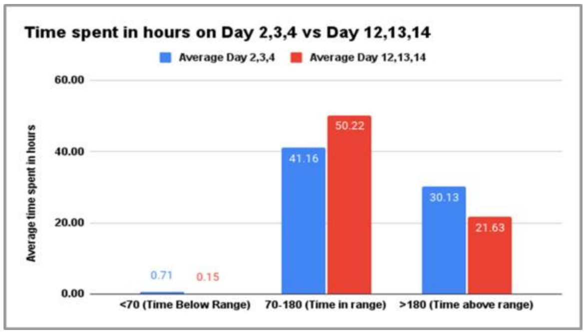


Figure 1 – Continuous glucose monitoring metrics from day 1 to day 14

Personalized life coaching interventions of SDRMP resulted in a significant increase in TIR (22.01%, p<0.001) from day 1 to day 14 and a significant correction of TAR by 28.21% and TBR by 78.63% (p<0.001 for both). The average estimated HbA1c decreased from 7.2±1.7 at baseline (days 2, 3, 4) to 6.7±1.3 at the end of study (days 12, 13, 14) (figure 2).

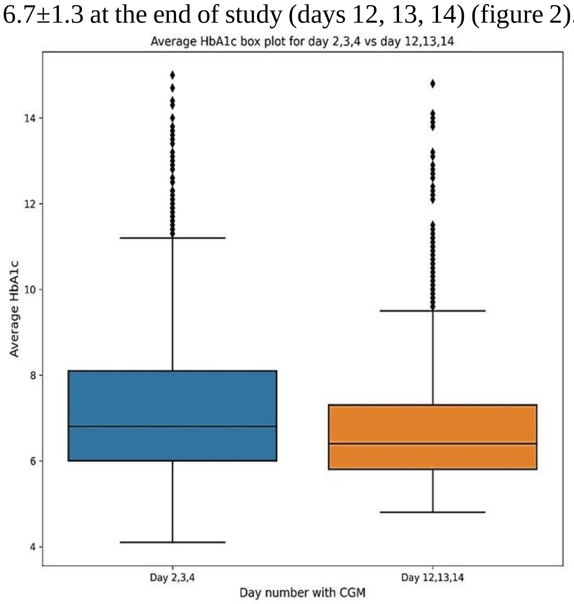


Figure 2 - The average HbA1c from day 1 to day 14

## IV. DISCUSSION

Until recently, HbA1c has been the gold standard for managing glycemic status.[9] However, HbA1c fails to capture BG variations [within a day or between days], and episodes of hyperglycemia or hypoglycemia.[12,13] Moreover, certain conditions such as ethnicity, iron deficiency, pregnancy, uremia, hemolytic anemia, and some hemoglobinopathies can alter sensitivity of HbA1c.[14–16]

CGM has helped to overcome and complement such limitations. CGM can help in implementing strict glycemic control and glucose homeostasis dynamically in real-time. CGM can be an effective tool in providing personalized diabetes management.[17–20] The role of CGM in glycemic control of type 1 diabetes (T1D) has been well established by multiple large, multicenter, randomized trials such as HypoDE,[17] IN CONTROL,[21] DIAMOND,[15] etc. However, the CGM's role and utility is still evolving to improve outcomes in T2D patients who require multiple modalities of management like lifestyle modifications, oral medications and insulin therapy.[22–25] Recent studies have also suggested that TIR can significantly improve T2D related complications such as peripheral neuropathy,[25] chronic kidney disease,[25] diabetic retinopathy,[24,26] cardiovascular mortality,[27] corneal nerve fiber loss,[23] carotid intima-media thickness,[28] macrovascular and microvascular,[2,29,30] etc. Outcomes from recent study also favour the use of CGM as a management and educational tool, especially in patients' dependent on insulin therapy.[31] According to ADA 2023 Standards of Diabetes Care, CGM plays an important role in the management of select individuals with T2D, and all individuals on insulin therapy (both T1D and T2D).[32–34] CGM helps to improve glucose control, decreased hypoglycemia, and enhance self-efficacy.[32–34] CGM in selected patients with non-insulin requiring T2D also helps in reducing hypoglycemia and/or improve glycemic control.[35] In view of this, CGM was used in our study - allowing us to acquire the daily profiles and glycemic excursions of all our participants in real-time. Depending on the individual participant's GV, SDRMP health coaches intervened timely with personalized lifestyle interventions and SDRMP doctors with prompt therapy decisions.

For most people with T1D or T2D, a TIR above 70% is recommended. This can be achieved by aiming to spend less than 5% in TBR (<70 mg/dL) and less than 25% in TAR (>180 mg/dL).[10,16] Although there was a

22% improvement in TIR during the short duration of this study, it emphasizes the importance of striving for better and consistent control to achieve TIR >70% of the time. Digital therapy can play a significant role in helping individuals with T2D to gain increased control over their condition. In recent times, digital therapy is increasingly recognized as a valuable tool because of its accessibility, real time monitoring, personal guidance and support through expert counseling sessions and community groups all while facilitating remote monitoring by healthcare providers, allowing them to track patients progress and provide timely feedback.[36]

Our study also shows that tailor-made multicomponent intervention approaches focusing only on behavioral modifications, physical activity, and diet delivered with the help of digital therapy was highly efficient, and beneficial in controlling GV. No medication was added or changed for the participants during the study period of 14 days. Findings from this study is supported by our earlier retrospective study results, highlighting the importance of non-pharmacologic interventional approach for optimal diabetes management.[37]

The role of GV and its significant impact on the risk of diabetes complications are well known.[30,31,38] However, HbA1c which is recommended every three months does not reflect GV.[13,39] To understand and study such glycemic excursions in real-time, CGM was proven to be highly effective. A literature review conducted by Breyton et al.,[38] has also identified and highlighted the importance of glycemic variability as a key component in T2D dysglycemia, encouraging it to be used alone or along with classical markers. Our CGM-based study also showed improved glucose homeostasis with lowered GV over a period of 14 days.

One notable limitation of this study was the gender disparity among participants, with females accounting for only 27% of the total cohort size. A systematic review on 'Gender Differences and Barriers Women Face in Relation to Accessing Type 2 Diabetes Care' in India, showed that women faced personal, sociocultural, health system, economic, psychological, and geographical barriers in accessing type 2 diabetes care.[40] There is a need for developing Non-communicable disease (NCD) control programmes that overcome these gender differences. Additionally, another limitation was the relatively short duration of the study. Conducting similar studies with longer durations, particularly randomized controlled trials (RCTs), would yield more substantial results in the same domain.

- Future directions

CGM takes about 24 hours to calibrate during which there might be false hypoglycemia recorded.[41] AI improvements to capture these incidents to be brought in as a feature. Diabetes management still requires significant human intervention without which delivering impactful insights can be challenging. AI can help to bridge this gap by machine learning technologies. Logging activities are of utmost importance during the CGM period without which understanding the sugar trends cannot be possible. Easy logging facilities like image and voice logging can ease the burden of manual logging in users.

## CONCLUSION

Our study shows that a multi-interventional SDRMP approach in individuals wearing a CGM device for 14 days can improve glycemic outcomes such as TIR and GV. Outcomes from the present study also strongly suggest the non-pharmacologic interventional approach based on real-time CGM data leading to insightful day-to-day treatment, decision-making, and optimal diabetes management. However, further prospective, long-term studies are warranted to obtain comprehensive data and a definitive picture.

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